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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/582,422	06/09/2006	Hoi-Ying N. Holman	LBNL-238 (IB-1867-US)	4848

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EXAMINER	
BRUTUS, JOEL F	

ART UNIT	PAPER NUMBER
3768	

MAIL DATE	DELIVERY MODE
01/23/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/582,422	HOLMAN, HOI-YING N.	
	Examiner	Art Unit	
	JOEL F. BRUTUS	3768	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *09 June 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *09 June 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Specification

1. The abstract of the disclosure should not contain any drawing, publication date, the name of the inventor, publication date, filing date. Applicant presents the first page of WO PCT along with all above information as the abstract. A new abstract of the disclosure is required and must be presented on a separate sheet, apart from any other text.

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-17, 19-24, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Afanassieva (Pub. No.: US 2001/0048077 A1) stand alone or in view of Dukor et al (Pub. No.: US 2002/0164810).

Regarding claims 1-17, 19-24, and 28, Afanassieva teaches methods of employing fiber optic and spectroscopy using fiber optic sensors in middle infrared region of the spectrum of wave numbers between (800 to 4000 cm^-1), apparatus and method that are used to diagnose skin tissue malignancy and pathological tissue or normal tissue in vivo, in vitro and ex vitro that is pertinent to the claimed invention. Afanassieva further teaches diagnostics of tissue in vivo, optical spectroscopy, Fourier transform techniques in combination with fiber optics and sensors. Tissue measurements are performed in the middle infrared and a fiber optic probe that is in direct contact with the tissue [see 0045, fig 1]. The optical scheme consists of spectrometer, light from IR source passes through an interferometer and focused into optical fibers and fiber probe to input and output infrared radiation via focusing lenses [see 0046]; reflected light that is collected from tissue fiber interface onto a detector that is preferably a nitrogen-cooled MCT detector [see 0047 and fig 3].

Probes preferably silver halide fibers can be bent to form an angle creating different probe tips depending on the size of the tissue; MIR fiber tip probe covering a larger tissue segment; forming a tip probe for detection of smaller areas of tissue and this probe is suitable for detection of normal and malignant tissues [see 0048]. A needle tip touches a tissue surface and the probe can be used in minimally invasive diagnostics like breast cancer [see 0048]; endoscope or catheter with additional fiber optic cable [see 0049]. The tips of the probe can be changeable for use in biopsy and endoscopic applications; specialized tip size and configuration that allow the collection or scattering of IR light for different type of tissue examinations [see 0049]. IR spectra in the wave number ranges of 800 to 1500 cm^-1, 1500 to 1900 cm^-1, 2700 cm^-1 to 3700 cm^-1 and the ranges can be extended to near and far infrared [see 0051]. Means for comparing band structure, peak positions, peak ratios etc. including visual display of the spectra to be compared. Means for comparing can be superimposed, calculating difference between spectra and subtracting one spectrum from another spectrum in order to reveal differences [see 0057]; comparing normal and premelanoma tissues [see 0058] and microcomputer or computer system [see 0047].

Afanassieva doesn't teach inserting the catheter into a blood vessel or inflammatory conditions, tunable system for the source.

However, Afanassieva teaches using the catheter for in vivo and invasive diagnostic applications that can be used for evaluating malignancies.

Dukor et al teaches infrared spectra of the extra cellular material in a biological sample may carry a spectral feature or maker that is a signature of presence of

pathology [see 0021]. Infrared absorption spectral measurement is performed in the reflective mode or transmission mode [see 0023]. Comparing infrared spectra of samples having pathology with infrared spectra of normal samples [see 0023]. Measuring absorbance spectral intensity using an infrared imaging device that a focal plane array detector [see 0028]; examining peak intensity of about 1280 cm^-1 [see 0025]; infrared image of a sample can be obtained with a single element detector by point-by-point scanning. The infrared absorbance spectral measured from the region can be used to determine the existence of marker [see 0032]; the device can be used to diagnosed for malignancy, inflammatory processes [see 0033]. Wave number around 1280 cm^-1 is effective for pathology detection [see 0009].

Dukor et al also teaches a step scan interferometer that includes a collimated glowbar infrared source [see 0054]; a rapid scan mirror, a Cassegrainian mirror which focuses the infrared light to the sample [see 0054]. A computer with a software application for IR imaging data collection and spectroscopy analysis [see 0060]; an acousto-optical tunable filter or liquid crystal tunable filter could be used to switch back and forth between the wavelengths of the two baselines points to obtain slope measurement [see 0063].

Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to combine these references; for the purpose of providing evaluation of malignancy with higher precision and greater precision; providing a more pronounced tissue spectrum. One with ordinary skill in the art would be motivated to use the catheter into a blood vessel for the purpose of accessing hidden areas of the

heart that may be malignant; thereby prescribing the best possible treatments available and/or creating passage in areas that are clotted. Using bright light in order to enhance visualization, thus increasing signal to noise ratio.

5. Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Afanassieva (Pub. No.: US 2001/0048077 A1) stand alone or in view of Dukor et al (Pub. No.: US 2002/0164810) as applied to claim 1 and 10 above and further in view of Corenman et al (US Pat: 4,817,013).

Regarding claim 18, all other limitations are taught as set forth by the above combination. The above combination doesn't teach customized bandwidth and special gain for DC or AC preamps.

However, Corenman et al teaches preamp [see 6C]; fig 4A shows AC/DC separation circuit in the amplifiers that receive signal output from three infrared detectors

Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to combine these references; for the purpose of providing a more efficient system by improving its performance. The above combination teaches multiple different bandwidths that could be customized along with this teaching; to provide great precision and accuracy.

6. Claim 25 is rejected under 35 U.S.C. 103(a) as being unpatentable over Afanassieva (Pub. No.: US 2001/0048077 A1) stand alone or in view of Dukor et al

(Pub. No.: US 2002/0164810) as applied to claim 1, 10 and 21 above and further in view of Soller et al (Pub. No.: US 2002/0151774).

Regarding claim 25, all other limitations are taught as set forth by the above combination.

The above combination doesn't teach spectrophotometer.

However, Soller et al teaches a spectral measurement of a native, diagnostic, or treatment component in blood or tissue, illuminates the back of the eye and collects returned light that passes through and been reflected from choroidal or retinal tissue [see abstract]. Soller et al teaches detecting light with a spectrophotometer that can be synchronized with a light directing element [see 0045].

Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to combine these references; for the purpose of providing light intensity measurement with great accuracy.

7. Claims 26 and 27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Afanassieva (Pub. No.: US 2001/0048077 A1) stand alone or in view of Dukor et al (Pub. No.: US 2002/0164810) as applied to claims 1, 10 and 21 above and further in view of Kittrell et al (US Pat: 4,913,142).

Regarding claims 26 and 27, all other limitations are taught as set forth by the above combination.

The above combination doesn't teach rotating the fiber optic cable radially within body lumens, performing 360 degree spectral analysis of body lumens.

However, Kittrell et al teaches a laser catheter wherein fiber optics carrying laser light are mounted in a catheter for insertion into an artery [see abstract]; flexible catheter body with a lumen [see column 7 lines 42-45]. Kittrell et al teaches the use of a guide wire to allow the catheter to pivot and rotary motion and advancing into the tissue in a helical motion [see column 16 lines 1-10].

Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to combine these references; for the purpose of providing a complete coverage analysis of the blood vessel being examined and acquiring information of surrounding areas that may be hidden; and to provide a controlled delivery of light to the area. An artisan would be able to rotate the fiber optic cable as taught above within body lumens at various locations and for 360 degree for the same reason above.

Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to JOEL F. BRUTUS whose telephone number is (571)270-3847. The examiner can normally be reached on Mon-Fri 7:30 AM to 5:00 PM (Off alternative Fri).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571)272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/J. F. B./
Examiner, Art Unit 3768

/Long V Le/
Supervisory Patent Examiner, Art Unit 3768